



FEB 12 2009

## 510(k) Summary

### LDR Spine USA ROI-C Partial Vertebral Body Replacement System

#### 1. Owner's Name & Address

LDR Spine USA  
4030 West Braker Lane, Suite 360  
Austin, TX 78759

Phone: (512) 344-3333  
Fax: (512) 344-3350

#### 2. Contact Person

Noah Bartsch MS, RAC,  
Manager, Clinical, Regulatory & Quality Affairs  
LDR Spine USA  
4030 West Braker Lane, Suite 360  
Austin, TX 78759

Phone: (512) 344-3319  
Fax: (512) 344-3350  
Email: noahbartsch@ldrspine.com

#### 3. Date 510(k) Summary Prepared

December 23, 2008

|                |  |
|----------------|--|
| 4. Trade Name  | LDR Spine ROI-C System   |
| Common Name    | Spinal Partial Vertebral Body Replacement Device                               |
| Classification | MQP<br>Spinal Intervertebral Body Fixation Orthosis – Class II<br>per 888.3060 |

#### 5. Legally Marketed Equivalent Predicate Device

LDR Spine ROI-C Partial Vertebral Body Replacement System (K080728)  
LDR Spine MC+ Partial Vertebral Body Replacement System (K043479)



a passion for innovation

## **6. Device Description**

The ROI-C Implants are D-shaped blocks in a variety of heights and length x width combinations. The ROI-C implants feature a closed graft space and the inferior and superior surface of the devices have a pattern of teeth to provide increased stability. The devices are manufactured from radiolucent PEEK, and are compatible with titanium anchor plates available for use with the ROI-C system.

The purpose of this submission is to obtain clearance for a modified design of the ROI-C implants.

## **7. Intended Use of the device**

The ROI-C is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a partial vertebral body replacement in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation. The ROI-C is intended to be implanted in pairs. Supplemental internal fixation is required to properly utilize this system.

## **8. Non-Clinical Performance Data**

Results of the non-clinical analysis and verification activities indicate that the proposed ROI-C system is substantially equivalent to the predicate device system.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

LDR Spine USA  
% Mr. Noah Bartsch, MS, RAC  
Manager, Clinical, Regulatory & Quality Affairs  
4030 West Braker Lane, Suite 360  
Austin, Texas 78759

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 12 2009

Re: K083857

Trade/Device Name: LDR Spine ROI-C Implant  
Regulation Number: 21 CFR 888.3060  
Regulation Name: Spinal intervertebral body fixation orthosis  
Regulatory Class: II  
Product Code: MQP  
Dated: January 23, 2009  
Received: January 26, 2009

Dear Mr. Bartsch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Noah Bartsch

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use Statement

Page 1 of 1

510(k) Number (if known):

Device Name: LDR Spine ROI-C Implant

### Indications for Use:

The ROI-C is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a partial vertebral body replacement in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation. The ROI-C is intended to be implanted in pairs. Supplemental internal fixation is required to properly utilize this system.

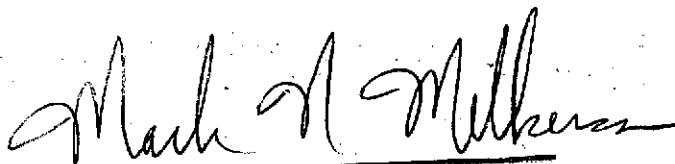
Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use         
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

510(k) Number   K083857